

REMARKS

This Amendment is submitted in reply to the non-final Office Action dated April 3, 2009. No fee is due in connection with this Amendment. The Director is authorized to charge any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-727 on the account statement.

Claims 1-4 and 6-11 are pending in this application. Claim 5 was previously canceled without prejudice or disclaimer. In the Office Action, Claims 1-4 and 6-11 are rejected under 35 U.S.C. §112. Claims 1-4 and 6-11 are further rejected under 35 U.S.C. §103. In response, Claims 1-3 and 8-10 have been amended and Claims 12-17 have been newly added. The amendments do not add new matter. The new claims do not add new matter. At least in view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the objections and rejections should be withdrawn.

In the Office Action, Claims 1-4 and 6-11 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Patent Office asserts that the phrase “lifts up only between 5 and 50% of the length of the culture chamber” in independent Claims 1 and 8-9 is indefinite because it is unclear whether 5 to 50% of the culture chamber is lifted by the plate, or whether the distance that the culture chamber is lifted is equal to 5 to 50% of the length of the culture chamber. See, Office Action, page 2, lines 20-22; page 3, lines 1-3. In response, Applicants have amended independent Claims 1 and 8-9 to recite “a plate that lifts up only a portion of the culture chamber, wherein the portion of the culture chamber lifted by the plate is between 5 and 50% of the length of the culture chamber” as suggested by the Patent Office. See, Office Action, page 8, lines 11-16. These amendments do not add new matter. The amendments are supported in the Specification at, for example, page 1, paragraph 6; page 2, paragraph 13, lines 4-5; page 2, paragraph 23, lines 7-11; page 3, paragraph 25, lines 4-7. Thus, Applicants respectfully submit that it is clear that 5 to 50% of the length of the culture chamber is lifted by plate.

The Patent Office further asserts that the phrase “a wave induction mechanism comprising a plate that lifts” is indefinite because it is unclear whether the wave induction mechanism or the plate performs the lifting. See, Office Action, page 3, lines 6-9. In response, Applicants have amended Claims 1 and 8-9 to recite a “wave induction mechanism comprising:

a plate that lifts.” These amendments do not add new matter. The amendments are supported in the Specification at, for example, page 1, paragraph 6; page 2, paragraph 13, lines 4-5; paragraph 23, lines 1-14; page 3, paragraph 25, lines 4-7; Figs. 2-3. By providing a colon between the phrase “wave induction comprising” and the limitation “plate that lifts,” it is clear that it is the plate, not merely the wave induction mechanism, that performs the lifting.

With respect to Claim 2, the Patent Office asserts that the phrase “lifts up from 8 to 20% of the surface area of the lower part of the culture chamber” is also unclear. See, Office Action, page 3, lines 4-5. In response, Applicants have amended Claim 2 to recite a cell culture apparatus “wherein the portion of the culture chamber lifted by the plate is between 8 and 20% of the length of the culture chamber.” This amendment does not add new matter. The amendment is supported in the Specification at, for example, page 2, paragraph 23, lines 7-11; page 3, paragraph 25, lines 4-7. Applicants respectfully submit that Claim 2 clearly indicates that a portion which is between 8 and 20% of the length of the culture chamber is lifted by the plate.

The Patent Office further asserts that the limitation “wave induction system” in Claim 2 lacks sufficient antecedent basis because Claim 1 recites a “wave induction mechanism.” See, Office Action, page 3, lines 10-13. In response, Applicants have amended Claim 2 to remove the phrase “wave induction system” Thus, Applicants respectfully submit that Claim 2 has sufficient antecedent basis.

With respect to Claims 3 and 10, the Patent Office asserts that the limitations “to an angle of 1 to 90°” and “to an angle of 1 to 25°” are indefinite because it is unclear what the angles are relative to. See, Office Action, page 3, lines 14-17. In response, Applicants have amended Claims 3 and 10 to recite that the angles are “with respect to an initial position of the plate.” These amendments do not add new matter. The amendments are supported in the Specification at, for example, page 2, paragraph 23, lines 2-14; Fig. 3. Thus, Applicants respectfully submit that Claims 3 and 10 clearly define the angles in relation to an initial position of the plate as shown in Fig. 3.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4 and 6-11 under 35 U.S.C. §112, second paragraph, be withdrawn.

In the Office Action, Claims 1-4 and 6-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2005/0063250 A1 to Hubbard ("*Hubbard*") in view of U.S. Patent No. 6,190,913 B1 to Singh ("*Singh*"). In response, Applicants have amended independent Claims 1 and 8-9. At least in view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that, even if combinable, the cited references fail to disclose each and every element of independent Claims 1 and 8-9 and Claims 2-4, 6-7 and 10-11 that depend therefrom. Furthermore, one of ordinary skill in the art would have no reason to combine the cited references because *Hubbard* teaches away from *Singh*.

Currently amended independent Claims 1 and 8-9 recite, in part, a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism which is compatible with large scale up of a culture medium to an amount of at least 1000 L, the wave induction mechanism comprising: a plate that lifts up only a portion of the culture chamber, wherein the portion lifted by the plate is between 5 and 50% of the length of the culture chamber. These amendments do not add new matter. The amendments are supported in the Specification at, for example, Abstract, lines 1-5; page 1, paragraph 6; page 2, paragraph 13; paragraph 20, lines 7-13; paragraph 23, lines 1-11; page 3, paragraphs 25 and 27; Figs. 2-3. Because only a portion of the culture chamber must be lifted to induce the wave motion, the present claims provide a cell culture system which generates less pressure during mixing and is thus easier to scale up to large volumes. See, Specification, page 1, paragraph 4, lines 20-34; paragraphs 5-6. In contrast, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

For example, even if combinable, the cited references fail to disclose or suggest a wave induction mechanism including a plate that lifts a portion of the culture chamber, wherein the portion of the culture chamber lifted by the plate is between 5 and 50% of the length of the culture chamber as required, in part, by independent Claims 1 and 8-9. *Hubbard* is entirely directed to obtaining a wave or rocking movement in a bio bag by inflation/deflation of a pressurized bag(s). See, *Hubbard*, Abstract; page 1, paragraphs 12-13. Although *Hubbard* discloses an immovable plate 42 attached to the pressurized bag(s) 40, the plate does not lift any portion of the culture chamber. See, *Hubbard*, page 2, paragraph 38; Fig. 6. In fact, the Patent Office admits that *Hubbard* fails to disclose a plate which lifts the cell culture chamber and

instead relies on *Singh* for the claimed element. See, Office Action, page 6, lines 16-22; page 7, lines 1-9.

However, *Singh* also fails to disclose a plate that lifts a portion of the culture chamber, wherein the portion of the culture chamber lifted by the plate is between 5 and 50% of the length of the culture chamber. The Patent Office asserts that *Singh* discloses “a plate that has a pivot point which alternately rocks each side of the cell culture chamber.” See, Office Action, page 6, lines 20-22. However, the portion of *Singh* relied on by the Patent Office teaches that the plate supports the entire length of the culture bag and rocks the entire bag from side to side. See, *Singh*, Abstract, lines 4-7; column 3, lines 44-57; column 4, lines 8-21; Figs. 1 and 3. Nowhere does *Singh* disclose that the plate lifts only a portion of the culture chamber. Unlike *Singh*, the present claims provide a system which lifts only a portion of the culture chamber, thereby generating less pressure and making the system easier to scale up to large volumes. See, Specification, page 1, paragraph 4, lines 20-34; paragraphs 5-6. As such, *Singh* and, thus, the cited references fail to disclose a plate that lifts a portion of the culture chamber, wherein the portion of the culture chamber lifted by the plate is between 5 and 50% of the length of the culture chamber in accordance with the present claims.

Moreover, even if combinable, the cited references fail to disclose a wave induction mechanism which is compatible with large scale up of a culture medium to an amount of at least 1000 L. The Patent Office relies on *Singh* for disclosure of the claimed wave induction mechanism and asserts that *Singh* is compatible with large scale-up to volumes of 500 L. See, Office Action, page 8, lines 17-22; page 9, lines 1-5. However, nowhere does *Singh* disclose that its apparatus is capable of mixing amount of 1000 L or more. Instead, *Singh* merely discloses that its apparatus may be used up to a volume of 500 L. See, *Singh*, column 3, lines 41-43; column 5, lines 7-9 and 65-67; column 6, lines 30-31 and 63-66.

Acknowledging that *Singh* does not disclose scale-up of its apparatus to volumes of at least 1000 L, the Patent Office further asserts that “a two-fold increase in volume would likely be a matter of routine experimentation in the art.” See, Office Action, page 9, lines 7-9. However, contrary to the Patent Office’s assertion, the apparatus of *Singh* generates too high a pressure to be scaled up to large volumes of 1000 L or more. See, Specification, page 1, paragraph 4, lines 20-34; paragraph 5. Furthermore, one of ordinary skill in the art would have no reason to

perform routine experimentation on the apparatus of *Singh* in order to make the apparatus compatible with large scale-up to volumes of 1000 L or more because *Singh* expressly states that its invention “has been developed through many investigations to result in a low cost simple solution to the problem of medium-scale (100 ml to 500 liter) cell culture.” See, *Singh*, column 3, lines 41-43. Therefore, Applicants respectfully submit that the cited references fail to disclose a wave induction mechanism which is compatible with large scale up of a culture medium to an amount of at least 1000 L, as required, in part, by the present claims.

Furthermore, one of ordinary skill in the art would have no reason to combine the cited references because *Hubbard* teaches away from the wave induction mechanism of *Singh*. The Patent Office admits that *Hubbard* fails to disclose a plate which lifts up the cell culture chamber and instead relies on *Singh* for the claimed element. See, Office Action, page 6, lines 16-22; page 7, lines 1-9. However, in explaining problems with the prior art mixing systems, Hubbard expressly cites the rocking mechanism of Singh and teaches that “[s]uch a system requires the use of capital-intensive equipment, with components that are susceptible to wear. Additionally, the size of the bag that can be used with the [plate] is limited by the size of [the plate] and the lifting capability of its motors/hydraulics.” See, *Hubbard*, page 1, paragraphs 6-7. *Hubbard* further teaches that the use of hydraulic or other lifting equipment limits the size and volume of the bag that may be used. See, *Hubbard*, paragraph 9.

In contrast, *Singh* is entirely directed to a rocking mechanism which is moved by lifting equipment such as pneumatic pistons. See, *Singh*, column 4, lines 19-21; column 5, lines 23-36. *Singh* further discloses that its system may include hydraulics to move the rocking mechanism. See, *Singh*, column 4, lines 21-22. As such, one of ordinary skill in the art would have no reason to combine the apparatus of *Hubbard* because *Hubbard* teaches away from wave induction mechanisms which include motors or hydraulics as disclosed in *Singh*.

Accordingly, Applicants respectfully request that the rejection of Claims 1-4 and 6-11 under 35 U.S.C. §103(a) to *Hubbard* and *Singh* be withdrawn.

Applicants further note that Claims 12-17 have been newly added. The new Claims are fully supported in the Specification at, for example, page 2, paragraph 14, lines 10-13; paragraph 23, lines 7-11; page 3, paragraph 24, lines 1-3; Figs. 1-3. No new matter has been added thereby. Applicants respectfully submit that the subject matter as defined in the newly added claims is patentable over the cited art for at least substantially the same reasons as discussed above.

Specifically, with respect to Claims 12-14, Applicants respectfully submit that the cited references fail to disclose a wave induction mechanism comprising a motorized arm which raises the plate. As discussed previously, *Hubbard* is entirely directed to obtaining a wave or rocking movement in a bio bag by inflation/deflation of a pressurized bag(s). See, *Hubbard*, Abstract; page 1, paragraphs 12-13. Nowhere does *Hubbard* disclose a motorized arm which raises a plate. In fact, *Hubbard* expressly teaches that systems which include motors, hydraulics or other lifting equipment are costly and limit the size of the bag that may be used. See, *Hubbard*, page 1, paragraphs 6-9. As such, *Hubbard* fails to disclose or suggest a lifting mechanism such as a motorized arm.

Singh also fails to disclose lifting a plate using a motorized arm. *Singh* is entirely directed to a rocking mechanism which is moved by alternate actuation of pneumatic pistons. See, *Singh*, column 4, lines 19-21; column 5, lines 23-36. Although *Singh* discloses that “[o]ther actuation means such as hydraulic [or] electric may be employed,” nowhere does *Singh* disclose lifting its rocking mechanism using a motorized arm. See, *Singh*, column 4, lines 21-22. As such, the cited references fail to disclose a wave induction mechanism comprising a motorized arm which raises the plate as required, in part, by Claims 12-14.

Furthermore, with respect to Claims 15-17, Applicants respectfully submit that the cited references fail to disclose a plate with a length equal to between 5 and 50% of the length of the culture chamber. The Patent Office admits that *Hubbard* fails to disclose a plate which lifts the cell culture chamber and instead relies on *Singh* for the claimed element. See, Office Action, page 6, lines 16-22; page 7, lines 1-9. However, *Singh* merely discloses a rocking platform 1 which extends the entire length of the culture bag 4. See, *Singh*, column 3, lines 44-48; Figs. 1-3. Nowhere does *Singh* disclose a plate with a length equal to between 5 and 50% of the length of the culture bag. As such, the cited references fail to disclose a plate with a length equal to between 5 and 50% of the length of the culture chamber as required, in part, by Claims 15-17.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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